

**Internal distribution code:**

- (A)  Publication in OJ  
(B)  To Chairmen and Members  
(C)  To Chairmen  
(D)  No distribution

**D E C I S I O N**  
**of 24 November 2005**

**Case Number:** T 1056/03 - 3.2.02

**Application Number:** 94308533.2

**Publication Number:** 0659445

**IPC:** A61M 16/00

**Language of the proceedings:** EN

**Title of invention:**  
Nitric oxide delivery system

**Patentee:**  
Datex-Ohmeda, Inc.

**Opponent:**  
Siemens-Elema AG, Solna (Schweden)  
Messer Austria GmbH

**Headword:**  
-

**Relevant legal provisions:**  
EPC Art. 52(1), 54, 56

**Keyword:**  
"Novelty (yes)"  
"Inventive step (yes)"

**Decisions cited:**  
-

**Catchword:**  
-



Case Number: T 1056/03 - 3.2.02

**D E C I S I O N**  
of the Technical Board of Appeal 3.2.02  
of 24 November 2005

**Appellant:** Siemens-Elema AG, Solna (Schweden)  
(Opponent I) c/o Siemens AG  
Postfach 22 16 34  
D-80506 München (DE)

**Representative:** Samzelius, Roger Mikael  
Siemens-Elema AB  
P.O. Box 22 16 34  
D-80506 München (DE)

(Opponent II) Messer Austria GmbH  
Am Kanal 2  
AT-2352 Gumpoldskirchen (AT)

**Representative:** Jäger, Gerhard Fred  
Messer Griesheim GmbH  
Patent-, Lizenz- und Markenabteilung  
D-60270 Frankfurt am Main (DE)

**Respondent:** Datex-Ohmeda, Inc.  
(Proprietor of the patent) 3 Highwood Drive  
Tewsbury  
Massachusetts 01876 (US)

**Representative:** Hedley, Nicholas James Matthew  
Kilburn & Strode  
20 Red Lion Street  
London WC1R 4PJ (GB)

**Decision under appeal:** Decision of the Opposition Division of the  
European Patent Office posted 5 August 2003  
rejecting the opposition filed against European  
patent No. 0659445 pursuant to Article 102(2)  
EPC.

**Composition of the Board:**

**Chairman:** T. Kriner  
**Members:** S. Chowdhury  
A. Pignatelli

## Summary of Facts and Submissions

I. The appellant (opponent I) lodged an appeal against the decision of the opposition division relating to European patent No. 0 659 445, rejecting oppositions to the grant thereof. The decision was dispatched on 5 August 2003.

The appeal was received on 24 September 2003, the fee for the appeal already having been paid on 22 September 2003. The statement setting out the grounds of appeal was received on 18 November 2003.

II. The opposition was filed against the whole patent and based on Article 100(a) EPC (lack of novelty and inventive step) and Article 100(c) EPC. The opposition division decided that the patent met the requirements of the EPC and rejected the opposition, accordingly.

III. As regards Article 100(a) EPC following documents were of interest in the appeal procedure:

E1: WO-A-92/11887

E2: WO-A-92/10228

The question of Article 100(c) EPC was not an issue in the appeal procedure.

IV. Oral proceedings were held on 24 November 2005. The appellant's representative did not appear, although duly summoned, and the oral proceedings took place in his absence in accordance with Rule 71(2) EPC. Opponent II had informed the Board, by letter dated

15 September 2005, that it would not attend the oral proceedings.

Appellant had requested in its notice of appeal that the decision under appeal be set aside and that the patent be revoked.

Respondent (patent proprietor) requested that the appeal be dismissed.

V. Independent claim 1 reads as follows:

"A nitric oxide delivery system for connection to a supply of nitric oxide (10) having a known concentration and for providing a predetermined concentration of nitric oxide to a patient (42) receiving a breathing gas from a gas delivery system, characterised in that the nitric oxide delivery system comprises:

a flow transducer (46) for sensing the flow of gas delivered by the gas delivery system and providing a signal (60) indicative of such flow to a signal processor (56),

means (58) for providing a signal indicative of the predetermined concentration of nitric oxide to be delivered to the patient (42),

a flow control valve (14, 20, 24) controlling the flow of nitric oxide from the supply of nitric oxide (10), conduit means (25, 32) receiving the flow of the nitric oxide from said flow control valve and combining the flow into the flow of gas from the gas delivery system,

and said signal processor (56) being responsive to the signal from the flow transducer (46) and to the signal indicative of the predetermined concentration to provide a signal to the flow control valve (14, 20, 24) to establish a flow of nitric oxide through the control valve (14, 20, 24) to the conduit means (25, 32) in an amount sufficient to establish a nitric oxide concentration delivered to the patient (42) in the predetermined amount."

Claims 2 to 11 are dependent claims.

VI. The appellant and respondent argued as follows:

Appellant

Neither the patent proprietor nor the opposition division had identified any means in the subject-matter of claim 1 or the description of the patent in suit, which handled the problem of the instability of NO. A nitric oxide delivery system was claimed and whether this meant a system delivering NO or one suitable for doing so was only a semantic difference, not a constructional one.

None of the features of claim 1 was dependent in any way on the specific properties of NO, the system of claim 1 was only for adding an additional gas to another flow of gas. There was no structural difference between the subject-matter of claim 1 and the disclosure of E1, which subject-matter lacked novelty, accordingly.

The claimed subject-matter also lacked an inventive step in view of the combination of E1 and E2 since there were no features in the claimed system which were specific in any way due to what was being dosed.

Respondent

A nitric oxide delivery system was clearly a reference to a dedicated system for delivering nitric oxide, not just one suitable for doing so. A nitric oxide delivery system would be configured so that the NO would be in contact with oxygen over a short path only, and a system would be licensed for delivering NO only if it were so configured. The system of E1 was for delivering an anaesthetic and would not be deemed to be a nitric oxide delivery system and not licensed for so doing.

The claimed system was an add-on system for attaching to any breathing gas delivery system by virtue of including a gas flow transducer and a signal processor. Since the inputs of the processor were independent of the breathing gas delivery system itself the claimed system could be used with any breathing gas delivery system. These teachings were not in the prior art so that the claimed subject-matter also involved an inventive step.

### **Reasons for the decision**

1. The appeal is admissible.

2. *Novelty*

2.1 Claim 1 of the patent in suit relates to "A nitric oxide delivery system". This is quite clearly a system which delivers nitric oxide, and a system which delivers another gas is not a nitric oxide delivery system and cannot anticipate this. For this reason alone the nitric oxide delivery system of claim 1 is novel over the anaesthetic gas delivery system of document E1.

2.2 Not only does E1 not anticipate the claimed system for the above reasons, the apparatus of E1 is also clearly not suitable for delivering NO. E1 relates to apparatus for controlling the concentration of a component in a gas mixture in an anaesthetic system. The problem is to reduce the consumption of expensive anaesthetic (page 1, lines 14-24) and this is done by using a system in which the gas is re-cycled. Figure 1 shows the circulating system having one-way inhalation and exhalation branches connected to a patient element, with a CO<sub>2</sub> absorber in the inhalation branch for removing excess CO<sub>2</sub>. A device for controlling the concentration of a component (an anaesthetic) is inserted in the inhalation branch.

Although there is teaching that another gas may be substituted for the anaesthetic (last line of the abstract), for the following reasons, this gas cannot be NO.

Firstly, as noted above the system re-cycles the anaesthetic, so if NO were to be used instead this would give the NO plenty of time to oxidise making the

system dangerous to use. Secondly, it is stated in the paragraph linking pages 3 and 4 that the unit (7) must be mounted at a distance from the patient for fear of contamination, which will also give the NO time to oxidise in the gas mixture which contains O<sub>2</sub>.

On page 4, line 11 of E1 it is stated that the apparatus may be used in an open anaesthetic system, but it is not clear how this would solve the stated problem or allow the anaesthetic concentration to be measured upstream of the point 30 of anaesthetic introduction (see E1, page 5, lines 11, 12, 27, 28).

Therefore, the system of E1 is not only unsuitable for delivering NO, such use would be positively dangerous for the patient.

2.3 The appellant argues that there is no feature in the apparatus of claim 1 which renders the apparatus dedicated to delivering NO. This argument is incorrect for the reasons set out in point 2.1 above. The claimed apparatus may be attached at the exit of a gas delivery system and immediately upstream of a patient, rather than at some intermediate point of the gas flow circuit, so that the NO, after being mixed with oxygen, may be delivered immediately to the patient.

2.4 Since no other available prior art document discloses all the features of claim 1 the subject-matter of claim 1 is novel.



3. *Inventive step*

3.1 Although the apparatus of E1 has many features in common with claim 1, this cannot be the closest prior art since it relates to a completely different apparatus as regards purpose, gas, manner of use, etc. A person skilled in the art wishing to improve known apparatus for delivering NO would never start from the apparatus of E1.

Instead, apparatus which is dedicated to delivering NO must form the basis of any improvement of NO delivering apparatus. For these reasons E2 is the closest available prior art document.

3.2 The patent relates to a NO delivery system for providing a predetermined concentration of NO to a patient receiving a breathing gas from a gas delivery system. A hospital may have different gas delivery systems, e.g. gas mixers for delivering a mixture of oxygen and an anaesthetic, mechanical ventilators, manual bags, etc. The object of the invention is to provide an add-on nitric oxide delivery system which can be used with any available gas delivery system (paragraphs 7, 12, 27, 28, 38 of the patent).

The claimed NO delivery system forms an add-on unit which may be connected to a NO source (which could be a bottle as shown or a NO pipe in the hospital) and to a gas delivery system. The claimed system automatically includes means to measure the gas flow rate in the gas delivery system and adjust the NO supply accordingly, and can therefore, be added on as a unit to any available gas delivery system. All inputs to the CPU

are independent of the gas delivery system itself, so that the unit may be used with any ventilator without modifying it or requiring the ventilator to have a special feature such as a flow meter. The claimed system may be used with any gas delivery system for the further reason that inputs to the signal processor are from the NO system itself, there is no input from the gas delivery system.

- 3.3 Since neither the technical problem set out above nor the use of an add-on unit as defined in claim 1 is known or suggested in the prior art, the claim also involves an inventive step.

## **Order**

**For these reasons it is decided that:**

The appeal is dismissed.

The Registrar:

The Chairman:

V. Commare

T. Kriner